

MAY 11 2000

**PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)**

807.92 (a):

1. *Submitter's Name:* STC Technologies, Inc.
Address: 1745 Eaton Avenue, Bethlehem, PA 18018
Telephone Number: (610) 882-1820
Contact Person: R. Sam Niedbala, Ph.D., BCFE
Date Prepared: 5/9/00
2. *Device Name:*
Proprietary Name: Cocaine Metabolite Intercept™ MICRO-PLATE EIA
Usual Name: Cocaine Metabolite Intercept™ System
Classification Name: Enzyme Immunoassay, Cocaine and Cocaine Metabolites
3. *Device to Which Substantial Equivalence Is Claimed:*
STC Cocaine Metabolite MICRO-PLATE EIA (OraSure® Application); K982061

4. *Description of Device:***Principle of the Assay**

The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA is a competitive immunoassay for the detection of cocaine and cocaine metabolites in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for cocaine or cocaine metabolites, there is a competition between cocaine and/or cocaine metabolite and the enzyme labeled hapten to bind the antibody fixed onto the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured at 450 nm is inversely proportional to the amount of cocaine or cocaine metabolite present in the specimen or calibrator/control. Because currently there are no SAMHSA assigned cutoffs for cocaine testing using oral fluid, STC recommends a cutoff of 5 ng/mL when testing oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. This cutoff is based on the results of clinical trials with oral fluid and is within the limit of detection by the STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA.

5. *Intended Use Statement:*

The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of cocaine and cocaine metabolites in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. **For In Vitro Diagnostic Use.**

The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

6. a. *Summary of Technological Characteristics:*

The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA is based on the principle of solid phase competitive enzyme immunoassay. This application is for the use of the STC Cocaine Metabolite Intercept™ EIA as a screening tool for the detection of cocaine and cocaine metabolites using specimens collected with the Intercept™ DOA Oral Specimen Collection Device manufactured by Epitepe, Inc., Beaverton, Oregon.

K001197

b. Summary of Performance Data:

The performance characteristics of the STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA are summarized below. This information concludes that the performance of this device is essentially equivalent to the legally marketed predicate device.

| | Proposed: Cocaine Metabolite Intercept™ MICRO-PLATE EIA | Previously Cleared (K982061): Cocaine Metabolite MICRO-PLATE EIA (OraSure® Application) |
|-------------------------------------|--|--|
| Performance Characteristics: | | |
| Precision | | |
| Intra-assay %CVs | 0 ng/mL: 3.7 2.5 ng/mL: 3.4 5.0 ng/mL: 4.3 7.5 ng/mL: 7.6 | 0 ng/mL: 6.2 5 ng/mL: 5.0 10 ng/mL: 7.0 50 ng/mL: 11.2 |
| Inter-assay %CVs | 0 ng/mL: 8.0 2.5 ng/mL: 9.0 5.0 ng/mL: 9.6 7.5 ng/mL: 10.5 | 0 ng/mL: 5.9 5 ng/mL: 5.4 10 ng/mL: 7.1 50 ng/mL: 10.8 |
| Limit of Detection | 1.5 ng/mL | < 5.0 ng/mL |
| % Cross-Reactivity | | |
| Cocaethylene | 200 | 94 |
| Cocaine | 64 | 12 |
| Ecgonine | 0.4 | 0.1 |
| Ecgonine Methyl Ester | 0.1 | 0.4 |
| Clinical Accuracy | 93.2% agreement as compared to GC/MS/MS. | 92.0% agreement as compared to GC/MS. |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 11 2000

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
STC Technologies, Inc.
1745 Eaton Avenue
Bethlehem, Pennsylvania 18018-1799

Re: K001197
Trade Name: STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA
Regulatory Class: II
Product Code: DIO
Dated: April 4, 2000
Received: April 11, 2000

Dear Dr. Niedbala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

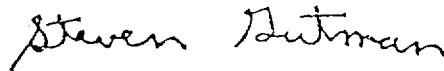
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K001197

Device Name: STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA

Indications For Use: The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of cocaine and cocaine metabolites in oral fluid collected with the Intercept™ Drugs of Abuse (DOA) Oral Specimen Collection Device. For In Vitro Diagnostic Use.

The STC Cocaine Metabolite Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K001197

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON
ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____